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| 09/996,878  | 11/30/2001  | Richard E. Fulton III | 216226US-25 CONT               | 4138             |
| 34263   | 7590        | 10/03/2005            |                                |                  |
| O'MELVENY & MEYERS LLP<br>610 NEWPORT CENTER DRIVE<br>17TH FLOOR<br>NEWPORT BEACH, CA 92660 |             |                       | EXAMINER<br>SZMAL, BRIAN SCOTT |                  |
|   |             |                       | ART UNIT                       | PAPER NUMBER     |
|   |             |                       | 3736                           |                  |

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/996,878

Applicant(s)

FULTON ET AL.

Examiner

Brian Szmal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 53-67, 69-72, 75, 76, 80 and 83-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 53-67, 69-72, 75, 76, 80 and 83-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2-14-05.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 69, 75 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The current specification, as well as the provisional applications to which the current application claims priority, fail to provide support for a bioabsorbable sponge as currently claimed in Claim 69. The listing of the types of materials the bioabsorbable element (page 9, lines 4-8, as stated in the Remarks filed on September 10, 2004) does not provide any support for a bioabsorbable sponge. The current specification, as well as the provisional applications to which the current application claims priority, fail to provide any support for the imageable matter comprising ions. The disclosure of radiographic iodine, contrary to the disclosure in the Remarks filed on September 10, 2004, is not an ion. Furthermore, the disclosure in the current specification on page 8, lines 7-13 does not provide support for claims 75 and 83, since the current specification only provides support for an ionized coating, and not an ionized radiographically imageable coating.

***Claim Objections***

3. Claims 72 and 80 are objected to because of the following informalities: In Claim 80, dependent upon Claim 72, the claim recites the detectable marker is a gelatinous material, however Claim 72 recites the detectable marker comprises a collagenous material. It is unclear to the Examiner if Claim 72 should recite the use of a gelatinous material or if Claim 80 should depend upon Claim 53 instead. Based on the current Claim 80, the Examiner will examine the claim as though the Claim depends upon Claim 53 instead of Claim 72. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 53-61, 65-67, 69, 71, 80, 83 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Cragg et al (6,071,301).

Cragg et al disclose a method for facilitating hemostasis in a biopsy tract and further disclose introducing into the site a detectable marker that remains present at the site in sufficient quantity to permit detection of the site for at least a predetermined first time period after introduction and does not interfere with imaging at a predetermined second time point after introduction; the detectable marker is imageable, and wherein the marker remains present at the site in sufficient quantity to allow detection of the site by imaging of the marker at the first time point but clears sufficiently from the site to not

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interfere with imaging of the tissue adjacent the site at the second time point; the imaging method comprises fluoroscopy; the marker is detectable by palpation; detection is done by imaging the marker; the palpable marker is comprised of a gelatinous material; the marker is visually detectable; the marker is colored with a substance selected from the group of a dye or a coloring agent; the detectable marker comprises a detectable material that will interfere with imaging of tissue adjacent thereto and remains present at the site in sufficient quantity to permit location of the site by imaging until the first time point but clears sufficiently from the site to not interfere with imaging of tissue adjacent the site at the second time point; the detectable marker comprises material that is detectable by radiographic, sonographic or MRI imaging means; the detectable marker comprises a sponge; the marker comprises a flowable material; the imageable matter comprises ions; and the detectable marker comprises a gelatinous material having radiographically imageable matter combined therewith. See Column 3, lines 26-29; Column 7, lines 24-28; Column 8, lines 35-37 and 49-55.

Even though Cragg et al does not explicitly disclose the types of imaging used to image the marker, the marker comprises a contrast agent that would inherently enable the marker to be imaged by various means of imaging equipment, including x-ray, sonograms and MRI. Furthermore, the disclosed sponge would be palpable due to the different consistency of the sponge in relation to the surrounding tissue, and the differing consistency would also allow the marker to be detectable via sonograms as well as MRI. The disclosed contrast agent would also allow the marker to be "visually

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detectable", since it is well known in the art that contrast agents are inherently colored agents. The disclosed contrast agent inherently comprises ions.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,071,301) as applied to claim 80 above, and further in view of Foerster et al (6,228,055 B1).

Cragg et al, as discussed above, disclose a means for detecting a bioabsorbable marker, but fail to disclose the imageable matter comprises a radiopaque marker.

Foerster et al disclose a means for marking tissue adjacent biopsy sites and further disclose the imageable matter comprises a radiopaque marker. See Column 13, lines 19-26 and 33-37.

Even though Foerster et al primarily discloses metallic markers, Foerster et al discloses in Column 13, lines 34-37, an alternative marker being comprised of a biodegradable polymer.

Since both Cragg et al and Foerster et al disclose means for marking biopsy sites, it would have been obvious to one of ordinary skill in the art to modify the marker of Cragg

et al to incorporate a radiopaque marker, as per the teachings of Foerster et al, since it would provide a means of relocating the biopsy site through radiographic imaging.

8. Claims 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,071,301) as applied to claim 53 above, and further in view of Amselem et al (5,576,016).

Cragg et al, as discussed above, disclose a means for marking a biopsy site, but fail to disclose a quantity of detectable material that if introduced into the site alone, would clear from the site such that a detectable quantity of the marker would no longer be present at the site at 2 weeks after introduction of the detectable marker, and a clearance delaying element that delays the clearance of the material from the site such that the material remains present at the site until at least 2 weeks after introduction and the material clears from the site to permit imaging of the tissue; the detectable material is a lipid; and the clearance delaying element is a gelatin.

Amselem et al disclose a solid fat nanoemulsion as a drug delivery vehicle, and further disclose a quantity of detectable material that if introduced into the site alone, would clear from the site such that a detectable quantity of the marker would no longer be present at the site at 2 weeks after introduction of the detectable marker, and a clearance delaying element that delays the clearance of the material from the site such that the material remains present at the site until at least 2 weeks after introduction and the material clears from the site to permit imaging of the tissue; the detectable material is a lipid; and the clearance delaying element is a gelatin. See Column 3, lines 57-67; Column 4, lines 1-22; Column 11, lines 61-67; and Column 12, lines 1-3.

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Even though Amselem et al primarily disclose a means of drug delivery, in Column 4, lines 9-14, Amselem et al disclose a means of imaging the lipid material to determine the phase of the lipid material, therefore showing the lipid material is viewable using various imaging means, which would also be capable of being used as a detectable marking means.

Since both Cragg et al and Amselem et al disclose means for visualizing a material, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Cragg et al to include the use of a lipid encapsulated with a gelatin, as per the teachings of Amselem et al, since it would provide an alternative means of marking a biopsy site.

9. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,071,301) as applied to claim 53 above, and further in view of Ersek et al (5,571,182).

Cragg et al, as discussed above, discloses a bioabsorbable detectable marker, but fail to disclose the marker comprises a liquid.

Ersek et al disclose textured micro implants and further disclose the marker comprises a liquid. See Column 7, lines 56-68.

Since Cragg et al and Ersek et al disclose the placement of bioabsorbable materials into tissue, it would have been obvious to one of ordinary skill in the art to modify the marker of Cragg et al to include the use of a flowable or liquid collagen injection at the tissue site, as per the teachings of Ersek et al, since a liquid marker is merely a variant of a marker that can include solid, semi-solid, or semi-porous.



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10. Claims 72, 75 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (6,071,301) as applied to claim 53 above, and further in view of Stinson (6,174,330 B1).

Cragg et al, as discussed above, disclose a bioabsorbable marker that also discloses a contrast agent inherently comprised of ions, but fail to disclose the detectable marker comprises a collagenous material having radiographically imageable matter attached thereto; and the radiographically imageable matter comprises a radiopaque marker.

Stinson discloses a bioabsorbable marker and further discloses the detectable marker comprises a collagenous material having radiographically imageable matter attached thereto; and the radiographically imageable matter comprises a radiopaque marker. See Column 2, lines 50-65; and Column 10, lines 32-54.

Since both Cragg et al and Stinson disclose bioabsorbable markers, it would have been obvious to one of ordinary skill in the art to modify the marker of Cragg et al to include the use of a collagenous material, as per the teachings of Stinson, since it would provide an alternative bioabsorbable material for the marker.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 53-67, 69-72, 75, 76, 80 and 83-85 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

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12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited prior art of Cragg et al (6,162,192) also discloses the same matter as Cragg et al (6,071,301). Scarborough (5,676,146) also discloses bioabsorbable implant containing an absorbable radiopaque marker.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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